

REMARKS

Claims 2; 14; 29; and 48 have been amended. Claims 1; 4 to 10; 13; 26 to 28; and 30 to 36 have been previously cancelled.

Claims 2; 12; 24; 25; 29; 47; and 48 remain for examination. Claims 3; 11; and 14 are withdrawn, pending reinstatement upon allowance of generic claim 2. Claim 2 is the sole independent apparatus, and claim 29 is the sole independent method claim.

Claims 2, 24, 25, 29, 47, and 48 as filed stand rejected under 35 U.S.C. § 102(b) based upon Freedman US 5,176,618 (Freedman). Claim 12 as filed stands rejected under 35 U.S.C. § 103(a) based upon Magovern US 5,979,456 (Magovern).

Claim 2 has been amended to define a structure sized and configured for implantation in tissue within a tongue along an airway. The structure comprises a shape memory material which is dynamically changeable, when activated by external stimulus, from a first kinetic phase state having mechanical properties not significantly affecting native tongue tissue conditions to a second kinetic phase state different than the first kinetic phase state and comprising an elastically loaded condition having mechanical properties that fixate native tongue tissue conditions to resist collapse of the tongue in the airway.

Claim 29 has been amended to be an independent method claim, defining the implantation of a structure having the features of apparatus claim 2 to resist collapse of a tongue in an airway by the application of external stimulus to affect a kinetic phase state change.

The Examiner's time and attention during an interview on June 5, 2007, is appreciated. Present at the interview were Nat Bowditch (President and CEO of Apneon Inc., the assignee of the instant application); Brian McCollum (Director of Quality Assurance of Apneon Inc.); Gabriela B. Tomescu, Esq. (Director Intellectual Property of Apneon); Ryan Boucher (one of the inventors named on the instant application); and the undersigned patent counsel for Apneon. Prior to the interview, applicant submitted a draft amendment of the claims. During the interview, claims 2; 12; 24; 25; 29; 47; and 48, as amended, were discussed, as was Freedman US 5,176,618 (Freedman) and Magovern US 5,979,456 (Magovern).

During the interview, Nat Bowditch discussed (with the aid of a Power Point® presentation) the clinical treatment of obstructive sleep apnea (OSA), which currently afflicts about 18 million Americans. Nat Bowditch discussed how the collapse of the tongue against the pharyngeal wall in an airway during sleep can cause the tongue to block the airway, giving rise to an OSA event. Nat Bowditch discussed the serious consequences of OSA, including the higher mortality rate of people afflicted by OSA when left untreated. Nat Bowditch also discussed the current treatments for OSA, namely Continuous Positive Airway Pressure (CPAP); maxillomandibular advancement (MMA); uvulopalatopharyngeoplasty (UPPP); and oral appliances. Nat Bowditch explained the problems with CPAP, including a high incidence (up to 65%) of non-compliance or discontinuance, as well as complaints of noise, nasal congestion, gum problems, discomfort, claustrophobia, and dry nose/mouth. Nat Bowditch also discussed the problems with MMA, including the highly invasive natures of the surgical procedures, the long recover time, and low patient appeal. Nat Bowditch further discussed the limited success rates of UPPP and oral appliances.

Ryan Boucher explained the solution defined in the amended claims. As defined in amended claim 2, a structure is sized and configured for implantation in tissue within a tongue along an airway. The structure comprises a shape memory material that is dynamically changeable between two kinetic phase states. In the first kinetic phase stage, the structure has mechanical properties not significantly affecting native tongue tissue conditions. In the second kinetic phase state, which is different than the first kinetic phase state, the structure comprises an elastically loaded condition having mechanical properties that fixate native tongue tissue conditions to resist collapse of the tongue in the airway. The kinetic phase states are activated by external stimulus and can thereby be controlled by an individual to enable normal speech and swallowing functions during daytime (the first kinetic stage) and to fixate native tissue in the tongue during sleep, i.e., nighttime (the second kinetic stage) to resist collapse of the tongue in the airway.

As discussed during the interview, Freedman's magnetically interactive systems do not teach or suggest a structure that is implanted in a tongue that is dynamically changeable between two kinetic phase states, as defined in the amended claims. Magovern does not teach or suggest

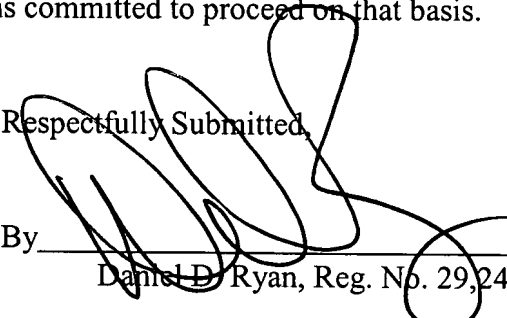
placement of a dynamically changeable structure in a tongue to fixate tissue and resist collapse of the tongue in an airway, as defined in the amended claims.

At the conclusion of the interview, the Examiner indicated that agreement was reached and that the proposed amendments to the claims (now incorporated in this formal Amendment B) appear to define over Freedman and Magovern. The Examiner indicated that the prior art search would be updated.

Claims 2; 12; 24; 25; 29; 47; and 48 are believed to be in condition for allowance. Applicant respectfully requests reinstatement of withdrawn claims 3; 11; and 14 should generic claim 2 be allowed. If the Examiner believes that questions or matters of clarification remain, which can be handled expeditiously by an interview, either in person or by telephone, to advance prosecution of this case, the applicant remains committed to proceed on that basis.

Respectfully Submitted,

By


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